

## Remarks

Claims 1-77 have been cancelled without disclaimer of or prejudice to the underlying subject matter. New claims 78-90 have been added. This application presently contains claims 78-90. No new matter is added by these amendments. Support for these amendments may be found in the original claims, the sequence listing, the figures, and throughout the specification, *e.g.*, at page 42, line 22 through page 43, line 24; page 50, line 13 through page 51, line 2; page 52, lines 11-14; page 54, line 5 through page 74, line 5; page 83, line 14 through page 85, line 15; page 88, lines 14-24; in Table 2 and Tables 4-6. Applicants respectfully request entry of the foregoing amendments and submit that these amendments put the application in condition for immediate allowance or appeal.

### *A. The Restriction Requirement*

Applicants acknowledge the finality of the restriction requirement but maintain their traversal on the grounds that the restriction is an undue division of Applicants' invention into an inordinately high number of allegedly independent and distinct inventions. To facilitate prosecution, however, Applicants have cancelled the non-elected claims without prejudice to or disclaimer of the underlying subject matter.

Applicants also acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully disagree that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent Examining Procedure. (*See* M.P.E.P., 8<sup>th</sup> ed., Incorporating Revision No. 1, Section 803.04, page 800-10.) However, in order to facilitate prosecution Applicants have removed non-elected sequences from the claims without prejudice to or disclaimer of the underlying subject matter.

***B. Information Disclosure Statement***

Applicants thank the Examiner for returning signed copies of the Forms 1449 for the information disclosure statements filed 19 November 2001, 15 January 2002, and 16 September 2002.

***C. Objection to the Specification***

The specification has been objected to on the grounds that it allegedly contains an embedded hyperlink and/or other form of browser-executable code. Office Action at page 3. The specification has been amended to remove the embedded hyperlinks and/or other forms of browser-executable code. No new matter enters by these amendments. The URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks or and/or other forms of browser-executable code. The specification as amended does not contravene stated PTO policy prohibiting live web links to other web pages, which might be commercial. (MPEP § 608.01(d)).

***D. Drawings***

Applicants thank the Examiner for indicating that the Draftsperson has approved the drawing.

***E. Claim Objections***

Claims 74, 75, and 77 were objected to because of an alleged informality in reciting "A method" instead of "The method." In order to facilitate prosecution, and without acquiescing to the propriety of these objections, Applicants have cancelled claims 74, 75, and 77 without disclaimer of or prejudice to the underlying subject matter. Applicants respectfully submit that the foregoing claim objections have been rendered moot. Applicants therefore respectfully request withdrawal of these objections.

Claims 73 and 74 have been objected to as being drawn to non-elected subject matter. Office Action at page 4. In order to facilitate prosecution, and without acquiescing to the propriety of these objections, Applicants have cancelled claims 73-74 without disclaimer of or prejudice to the underlying subject matter. Applicants respectfully submit that the foregoing claim objections have been rendered moot. Applicants therefore respectfully request withdrawal of these objections.

***F. Rejections under 35 U.S.C. § 112, first paragraph (Written Description)***

Claims 73-75 and 77 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at page 4. The Office states that "Applicant does not describe what the nucleic acid molecule having at least 15 nucleotides capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 or a complement thereof is." The Office further alleges that it is therefore "unclear from the instant specification that Applicant was in possession of the invention as broadly claimed." Office Action at page 5. Applicants disagree.

In order to facilitate prosecution, and without acquiescing to the Examiner's arguments, Applicants have cancelled claims 73-75 and 77 without disclaimer of or prejudice to the underlying subject matter. As such, Applicants direct this section of this Response (*i.e.*, the section addressing the alleged lack of written description support for claims 73-75 and 77) to new claims 78-90.

In the Office Action mailed December 11, 2002, the Examiner appears to suggest that an adequate written description of a genus of nucleic acid sequences requires a recitation of the complete sequence of every nucleic acid encompassed within the genus. Office Action at page 5 (*e.g.*, citing *Fiers* for the proposition that an adequate written description of a DNA requires "a description of the DNA itself"). Applicants disagree. An adequate written description of a genus of nucleic acids may be achieved by means of a "recitation of a representative number of

[members], ...or of a recitation of structural features common to the members of the genus.” *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Moreover, the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...*i.e.*, complete or partial structure, other physical and or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). (quoting from Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001)).

Moreover, Applicants respectfully submit that the instant specification complies with the written description requirement. Applicants’ specification provides the complete nucleotide sequence of SEQ ID NO: 2. As such, Applicants’ specification *prima facie* describes nucleic acid markers that may be used to screen for the presence of an rhg1 SCN resistant allele. Applicants’ specification describes the nucleic acid itself, and therefore, accords with the written description requirement as interpreted in *Fiers*.

Applicants disagree with the Office’s allegation that claims 73-75 and 77 contain subject matter that was not adequately described in the specification. However, in order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have cancelled claims 73-75 and 77 without prejudice to or disclaimer of the underlying subject matter. For at least the foregoing reasons, Applicants submit that the written description rejections under 35 U.S.C. § 112, first paragraph, have been overcome or rendered moot. Applicants therefore respectfully request that the written description rejections be withdrawn.

**G. *Rejections of claims 73-75 and 77 under 35 U.S.C. § 112, first paragraph (Enablement)***

Claims 73-75 and 77 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Office Action at page 6. The Office

states that “[i]t would have required undue trial and error experimentation by one of skill in the art at the time of Applicant’s invention to screen through a myriad of nucleic acid molecules having at least 15 nucleotides that are capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 that would allow for selection of a SCN resistant soybean in a reasonably predictable manner.” Office Action at pages 7-8. Applicants respectfully disagree.

In order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have cancelled claims 73-75 and 77 without disclaimer of or prejudice to the underlying subject matter. However, in the interests of expediting prosecution, Applicants address the Examiner’s arguments to the extent that they are relevant to new claims 78-90.

It is well-established law that “the enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Because Applicants need only establish a single mode of making and using the invention, and have done so in this case, Applicants have enabled the claimed invention.

The present specification indeed provides ample guidance to teach one of skill in the art how to make and use the claimed invention. For example, the specification provides methods for, and a working example of, screening plants to identify those plants that carry an *rhg1* SCN resistant allele by means of various markers including SSRs, SNPs, insertion/deletion polymorphisms (INDELs), AFLP markers, RFLP markers, RAPD markers, VNTR markers, phenotypic markers, and isozyme markers. *See, e.g.*, specification at page 54, line 5 through page 62, line 14; and Example 1. The specification describes the nucleotide position of single nucleotide polymorphisms (SNPs) and insertion/deletion polymorphisms (INDELs) in various soybean lines. *See, e.g.*, Table 2 and Table 4. This SNP and INDEL information is also correlated with soybean haplotypes. *See, e.g.*, Tables 2, 3, 4, and 5. The specification describes simple sequence repeat (SSR) polymorphisms and indicates the allele of each marker occurring in a soybean haplotype. *See, e.g.*, Table 4. The specification provides guidance for setting up breeding crosses, and describes how polymorphic markers are used to establish genetic linkage maps. *See, e.g.*, specification at page 62, line 15 through page 74, line 22. Examples of clones

comprising rhg1 and Rhg4 sequences from various soybean lines are also provided. *See, e.g.*, Table 6, and specification at page 80, lines 1-7.

To the extent that the Office suggests there is a requirement for *a priori* predictability without recourse to any experimentation, that position is without legal support. *Cf. Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) (“[t]hat some experimentation is necessary does not preclude enablement”). The proper test of enablement in such a situation is whether the disclosure “adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.” *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991).

The Office Action expresses concern that testing of the putative positives would entail screening through some false positives. Office Action at page 7 (citing to *Fourgoux-Nicol et al* and *Staub and Serquen*). This concern is misplaced. “It is not a function of the claims to specifically exclude...possible inoperative substances.” *Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) (citing *In re Dinh-Nguyen*, 492 F.2d 856, 858-59, 181 U.S.P.Q. 46, 48 (C.C.P.A. 1974)). The case law does not require “each and every compound within a claim to be equally useful for each and every contemplated application.” *Ex Parte Cole*, 223 U.S.P.Q. 94, 95 (B.P.A.I. 1983).

There is no legal requirement that each and every nucleic acid molecule encompassed by the claims be useful for every contemplated utility. What is required is that the art worker know how to determine, after reasonable experimentation, whether a particular nucleic acid molecule is useful for a particular utility. The Office Action has not contended, nor can it contend that this is unachievable with the nucleic acid molecules of the present claims. Instead, an improper test has been manufactured and applied which requires (without legal authority) demonstration of *a priori* knowledge of whether a particular molecule within the claimed genus would work.

Applicants respectfully disagree with the Office’s assertion that claims 73-75 and 77 contain subject matter that was not described in the specification in such as way as to enable one skilled in the art to make and/or use the invention without undue experimentation. However, in order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants

have cancelled claims 73-75 and 77 without disclaimer of or prejudice to the underlying subject matter. Applicants therefore submit that the enablement rejections under 35 U.S.C. § 112, first paragraph, have been overcome or rendered moot. Applicants therefore respectfully request that the enablement rejections be withdrawn.

***H. Rejection of claim 74 under 35 U.S.C. § 112, first paragraph (Enablement)***

Claim 74 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Office Action at page 8. The Office alleges that the invention employs “novel plants” that are essential to the claimed invention, and that such plants “must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public.” Office Action at page 8. The Office further asserts that “[i]f each of the soybean varieties is not publicly available then the requirement for a deposit of biological material must be perfected in order to enable the claimed invention.” Office Action at page 8. Applicants respectfully disagree.

In order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have cancelled claim 74 without disclaimer of or prejudice to the underlying subject matter. However, in the interests of expediting prosecution, Applicants address the Examiner’s arguments to the extent that they are relevant to new claims 78-90.

Applicants respectfully disagree that the claimed invention employs novel plants. For example, Applicants direct the Examiner’s attention to the Germplasm Resources Information Network (GRIN) Database, which is maintained by the National Plant Germplasm System of the Agricultural Research Service, of the United States Department of Agriculture. *See, e.g.*, [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_site\\_acc.pl?SOY%20Glycine%20max](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_site_acc.pl?SOY%20Glycine%20max). Applicants also refer the Examiner to the specification at page 69, lines 6 through 24; and Tables 2-4. Applicants further submit that the claims have been amended to remove references to the allegedly “arbitrary varietal designations such as ‘Jack.’” Office Action at page 8.

For at least these reasons, Applicants submit that the enablement rejection under 35 U.S.C. § 112, first paragraph, has been overcome or rendered moot. Applicants therefore respectfully request that the enablement rejection be withdrawn.

***I. Rejections under 35 U.S.C. § 112, second paragraph (Indefiniteness)***

***Rejection of Claim 73***

The Office alleges that the method of Claim 73 is indefinite because “[a]t step (A), the crossing step comprises crossing a first soybean having at least one rhg1 SCN resistance allele or an Rhg4 resistance allele, yet at step (B) one screens for both alleles.” Office Action at page 10. Applicants respectfully disagree. Nevertheless, in order to facilitate prosecution, Applicants have cancelled claim 73 without disclaimer of or prejudice to the underlying subject matter. Applicants respectfully submit that the grounds for the alleged indefiniteness rejection of claim 73 have been overcome or rendered moot. Applicants therefore respectfully request that the indefiniteness rejection be withdrawn.

The Office further alleges that Claim 73 is indefinite in the recitation of the phrase “specifically hybridizing at least under low stringency conditions.” Office Action at page 10. Applicants disagree. However, in order to facilitate prosecution, Applicants have cancelled claim 73 without disclaimer of or prejudice to the underlying subject matter. Applicants therefore submit that the grounds for the alleged indefiniteness rejection of claim 73 have been overcome or rendered moot, and respectfully request that the indefiniteness rejection be withdrawn.

The Office further alleges that Claim 73 step (B), subsections (i) and (ii) are indefinite in the recitation of “and is linked to said...” because it is unclear “if this limitation is referring to the second nucleic acid molecule of the subsection or the first nucleic acid molecule having at least 15 nucleotides.” Office Action at page 10. Applicants respectfully disagree. Nevertheless, in order to facilitate prosecution, Applicants have cancelled claim 73 without disclaimer of or prejudice to the underlying subject matter. Applicants therefore submit that the grounds for the alleged indefiniteness rejection of claim 73 have been overcome or rendered moot, and respectfully request that the indefiniteness rejection be withdrawn.



The Office alleges that Claim 73, (B)(ii) lines 2-3 is indefinite in the recitation of “said Rhg4 SCN resistance allele” due to a lack of proper antecedent basis within the claim. Office Action at page 10. Applicants disagree. However, in order to facilitate prosecution, Applicants have cancelled claim 73 without disclaimer of or prejudice to the underlying subject matter. Applicants therefore submit that the grounds for this indefiniteness rejection have been overcome or rendered moot, and request that the indefiniteness rejection of claim 73 be withdrawn.

Claim 73 also stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because “this appears to be an intended use limitation and does not clearly designate that “a soybean having SCN resistance is selected as stated in the preamble of the claim.” Office Action at page 11. Applicants disagree. Nevertheless, in order to facilitate prosecution, Applicants have cancelled claim 73 without disclaimer of or prejudice to the underlying subject matter. Applicants respectfully submit that the grounds for this indefiniteness rejection have been overcome or rendered moot. Applicants therefore request that the indefiniteness rejection of claim 73 be withdrawn.

#### ***Claims 73 and 75***

Claims 73 and 75 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite in the recitation of the phrase “is capable of specifically hybridizing.” Office Action at page 11. Applicants disagree. However, in order to facilitate prosecution, Applicants have cancelled claims 73 and 75 without disclaimer of or prejudice to the underlying subject matter. Applicants therefore submit that the grounds for this indefiniteness rejection have been overcome or rendered moot, and request that the indefiniteness rejections of claim 73 and 75 be withdrawn.

#### ***Claim 74***

Claim 74 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite “because the claim contains two Markush groups linked using the definitive conjunction “and” while claim 73 to which it is dependent clearly uses the alternative conjunction “or” in referring to the first soybean plant having an SCN resistant allele.” Office Action at page 11. The Office

further alleges that Claim 74 is in improper Markush format. *Id.* Applicants respectfully disagree. Nevertheless, in order to facilitate prosecution, Applicants have cancelled claim 74 without disclaimer of, or prejudice to, the underlying subject matter. Applicants respectfully submit that the grounds for this indefiniteness rejection have been overcome or rendered moot. Applicants therefore request that the indefiniteness rejection of claim 74 be withdrawn.

Claim 74 also stands rejected because the phrase “an Rhg4 SCN resistant allele” lacks proper antecedent basis in claim 73. Office Action at page 11. In order to facilitate prosecution, Applicants have cancelled claim 74 without disclaimer of, or prejudice to, the underlying subject matter. Applicants respectfully submit that the grounds for this indefiniteness rejection have been overcome or rendered moot. Applicants therefore request that the indefiniteness rejection of claim 74 be withdrawn.

Claim 74 also stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because “the sole designation of a plant by its breeding line name or number is arbitrary and creates ambiguity in the claims” Office Action at page 11. The Office further alleges that “the plant disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant.” Office Action at page 11. The Office suggests that amendment of the claim to refer to the deposit accession number of the claimed breeding line would obviate this rejection. Office Action at page 12.

Applicants disagree. Applicants further submit that the grounds for this indefiniteness rejection have been addressed in the above section H, which is directed to rejection of claim 74 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. In order to facilitate prosecution, Applicants have cancelled claim 74 without disclaimer of, or prejudice to, the underlying subject matter. For at least these reasons, Applicants submit that the grounds for the indefiniteness rejection have been overcome or rendered moot. Applicants therefore respectfully request that the indefiniteness rejection of claim 74 be withdrawn.

***Claim 77***

Claim 77 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite on the grounds that the phrase “an Rhg4 SCN resistant allele” lacks proper antecedent basis in claim 73. Office Action at page 12. Applicants respectfully disagree. Nevertheless, in order to facilitate prosecution, Applicants have cancelled claim 77 without disclaimer of or prejudice to the underlying subject matter. Applicants respectfully submit that the grounds for this indefiniteness rejection has been overcome or rendered moot, and request that the indefiniteness rejection of claim 77 be withdrawn.

***J. Rejections under 35 U.S.C. §102(e)***

Claims 73-75 and 77 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Lightfoot *et al.* (U.S. Patent 6,300,541 B1, filed 14 January 1997). Office Action at page 12. The Office alleges that “Lightfoot discloses that the O103<sub>512</sub> and SATT39 markers are linked to the rhg1 SCN resistant allele (see figure 23),” and that “Lightfoot also discloses a method using the parental soybean variety ‘Hartwig’ which comprises the Rhg4 SCN resistant allele in Example 8 at columns 32-35 and said method using parental soybean varieties comprising both the rhg1 SCN resistance allele and the Rhg4 SCN resistance alleles at column 33, lines 30-35.” Office Action at pages 12-13.

In order to facilitate prosecution, and without acquiescing to the Examiner’s arguments, Applicants have amended the claims to read on [a] method of introgressing an allele conferring soybean cyst nematode resistance into a non-resistant soybean plant comprising (A) crossing at least one soybean plant bearing an rhg1 SCN resistant allele with at least one soybean plant bearing an rhg1 SCN sensitive allele in order to form a segregating population, wherein said at least one soybean plant bearing said rhg1 SCN resistant allele is derived from one or more soybean lines selected from the group consisting of PI200499, A2869, PI404198B, PI404166, PI548988, PI507354, PI438489B, PI84751, PI407922, PI540556 and A2069, (B) screening said segregating population with one or more nucleic acid markers to identify an rhg1 SCN resistant allele, and (C) selecting one or more members of said segregating population having said rhg1 SCN resistant allele.

In order for a reference to anticipate a claimed invention, it must teach exactly what is claimed. *Titanium Metals Corp. v. Banner* 778 F.2d 775, 227 U.S.P.Q.2d 1766 (Fed. Cir. 1987), *cert. denied* 484 U.S. 1007 (1988). Whatever else Lightfoot *et al.* describes, it does not describe one or more soybean lines selected from the group consisting of PI200499, A2869, PI404198B, PI404166, PI548988, PI507354, PI438489B, PI84751, PI407922, PI540556 and A2069. In view of the preceding, Applicants submit that Lightfoot *et al.* does not anticipate new claims 78-90.

In view of the foregoing, Applicants respectfully submit that the grounds for this anticipation rejection has been overcome or rendered moot, and request withdrawal of the rejection of claims 73-75 and 77 under 35 U.S.C. §102(e).

### Conclusion

In view of the above, each of the presently pending claims is believed to be in condition for immediate allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is respectfully requested to contact Applicants' undersigned representative at 202.942.5512 to address any unresolved issues remaining in this application.

Respectfully submitted,



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